

AMENDMENT

Amendments to the Claims

1. (previously amended) A process for the determination of *H. pylori* antigen in a human fecal specimen which comprises:
 - (a) dispersing human fecal specimen in a sample diluent;
 - (b) contacting the fecal specimen in the diluent with a first antibody to form a complex of the antibody and the antigen;
 - (c) separating said specimen and said complex;
 - (d) exposing the complex to a second antibody and a portion of the second antibody reacting with said complex, one of said first and second antibody being selected from the group consisting of polyclonal *H. pylori* antigen specific antibodies, a plurality of monoclonal *H. pylori* antigen specific antibodies and mixtures thereof wherein such antigen specific antibodies bind to *H. pylori* antigen and do not react with different species and strains of *Helicobacter* or *Campylobacter*; and the other of the first and second antibody being a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and also binds to *H. pylori* antigen, one of said first and second antibody being bound to a solid carrier and the other being labeled with a detection agent; and
 - (e) detecting the amount of the labeled antibody in said complex and in turn determining the presence of *H. pylori* antigen in said fecal specimen.
2. (original) The process of claim 1 wherein the first antibody is bound to a solid carrier and the second antibody is labeled with a detection agent.
3. (original) The process of claim 1 wherein the first antibody is labeled with a detection agent and the second is bound to a solid carrier.
4. (original) The process of claim 1 wherein the sample diluent is a protein based diluent.

5. (original) The process of claim 1 wherein said first antibody is said genus directed monoclonal antibody and said second antibody is selected from the group consisting of polyclonal *H. pylori* antigen specific antibodies, a plurality of monoclonal *H. pylori* antigen specific antibodies and mixtures thereof.
6. (original) The process of claim 1 wherein the first antibody is labeled with a detection agent and the second is bound to a solid carrier.
7. (amended) The process of claim 5 wherein the sample diluent is a protein based diluent.
8. (original) The process of claim 1 wherein said first antibody is said genus directed monoclonal antibody and said second antibody is selected from the group consisting of polyclonal antibodies, a plurality of monoclonal antibodies and mixtures thereof specific for *H. pylori* antigen.
9. (original) The process of claim 4 wherein the sample diluent contains a protein selected from the group consisting of fetal bovine serum, normal goat serum, guinea pig serum, horse serum, casein, albumin, gelatin, and bovine serum albumin.
10. (original) The process of claim 1 wherein after exposing the complex to the second antibody, the complex is washed with a buffer that reduces cross-reactivity or otherwise improves the specificity of the assay.
11. (amended) A process for the determination of *H. pylori* in a fecal specimen which comprises:
 - (a) dispersing a human fecal specimen in a diluent;
 - (b) contacting the fecal specimen in the diluent with a first antibody reactive with *H. pylori* antigen bound to a solid carrier and a second labeled antibody reactive with *H. pylori* to form a complex of the antibodies and the antigen, one of said first and second antibody being selected from the group consisting of polyclonal *H. pylori* antigen specific antibodies, a plurality of *H. pylori* antigen specific monoclonal antibodies, and mixtures thereof wherein such antigen specific antibodies bind to *H. pylori* antigen and do not react with different species and strains of *Helicobacter* or *Campylobacter*; and the other of the first and second antibody

being a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and also binds to *H. pylori* antigen;

- (c) separating said specimen and said complex;
- (d) detecting the labeled antibody in said complex formed in step (b) and in turn determining the presence of *H. pylori* antigen in said fecal specimen.

12. (amended) A process for the determination of *H. pylori* in a fecal specimen which comprises:

- (a) dispersing a human fecal specimen in a sample diluent;
- (b) contacting the fecal specimen in the diluent with a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and binds to *H. pylori* antigen bound to a solid carrier to form a complex of the antibody and the antigen;
- (c) separating said specimen and said complex;
- (d) contacting the antibody-antigen complex formed in step (b) with a primary antibody specific for *H. pylori* antigen obtained from an antibody-producing species to produce an antibody-antigen-antibody complex wherein such antigen specific antibodies bind to *H. pylori* antigen and do not react with different species and strains of *Helicobacter* or *Campylobacter*;
- (e) removing the primary antibody not present in the complex from step (c);
- (f) contacting the antibody-antigen-antibody complex formed in step (e) with a secondary antibody, said secondary antibody being an antibody that specifically binds the antibody-producing species antibody, whereby said secondary antibody forms a complex with said antibody-antigen-antibody complex; and
- (g) determining the presence of *H. pylori* antigen in said fecal specimen by detecting the complex formed in step (f).

13. (amended) A kit for the determination of *H. pylori* in a fecal specimen including a plate of wells having bound thereto a genus directed monoclonal antibody that reacts with

different species and strains of *Helicobacter* or *Campylobacter* and also binds to *H. pylori* antigen, a protein-based sample diluent and a plurality of labeled antibodies selected from the group consisting of polyclonal *H. pylori* antigen specific antibodies, a plurality of monoclonal *H. pylori* antigen specific antibodies and mixtures thereof wherein such antigen specific antibodies bind to *H. pylori* antigen and do not react with different species and strains of *Helicobacter* or *Campylobacter*;

14. (amended) process for the determination of *H. pylori* in a fecal specimen which comprises:
 - (a) dispersing a human fecal specimen in a diluent;
 - (b) contacting the fecal specimen in the diluent with a first antibody reactive with *H. pylori* antigen bound to a solid carrier and a second labeled antibody reactive with *H. pylori* to form a complex of the antibodies and the antigen, one of said first and second antibody being selected from the group consisting of polyclonal antibodies for *H. pylori* antigen, a plurality of *H. pylori* antigen specific monoclonal antibodies, and mixtures thereof wherein such antigen specific antibodies bind to *H. pylori* antigen and do not react with different species and strains of *Helicobacter* or *Campylobacter*; and the other of the first and second antibody being a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and also binds to *H. pylori* antigen;
 - (c) separating said specimen and said complex;
 - (d) detecting the labeled antibody in said complex formed in step (b) and in turn determining the presence of *H. pylori* antigen in said fecal specimen.
15. (amended) A process for the determination of *H. pylori* in a fecal specimen which comprises:
 - (a) dispersing a human fecal specimen in a sample diluent;
 - (b) contacting the fecal specimen in the diluent with a genus directed monoclonal antibody that reacts with different species and strains of *Helicobacter* or *Campylobacter* and binds to *H. pylori* antigen bound to a solid carrier to form a

complex of the antibody and the antigen wherein such antigen specific antibodies bind to *H. pylori* antigen and do not react with different species and strains of *Helicobacter* or *Campylobacter*;

- (c) separating said specimen and said complex;
 - (d) contacting the antibody-antigen complex formed in step (b) with a primary antibody for *H. pylori* antigen obtained from an antibody-producing species to produce an antibody-antigen-antibody complex;
 - (e) removing the primary antibody not present in the complex from step (c);
 - (f) contacting the antibody-antigen-antibody complex formed in step (e) with a secondary antibody, said secondary antibody being an antibody that specifically binds the antibody-producing species antibody, whereby said secondary antibody forms a complex with said antibody-antigen-antibody complex; and
 - (g) determining the presence of *H. pylori* antigen in said fecal specimen by detecting the complex formed in step (f).
16. (amended) A kit for the determination of *H. pylori* in a fecal specimen including a plate of wells having bound thereto a genus specific monoclonal antibody for *H. pylori* antigen, a protein-based sample diluent and a plurality of labeled antibodies specific for *H. pylori* antigen wherein such antigen specific antibodies bind to *H. pylori* antigen and do not react with different species and strains of *Helicobacter* or *Campylobacter*.